

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 18-10568-RGS

DUSA PHARMACEUTICALS, INC.

v.

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH,  
BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG

MEMORANDUM AND ORDER ON  
BIOFRONTERA'S MOTION TO EXCLUDE  
THE OPINION OF DR. JEFFREY STEC

October 9, 2020

STEARNS, D.J.

Biofrontera moves to exclude the lost profits analysis of DUSA's damages expert, Dr. Jeffrey Stec. In Biofrontera's view, the accused BF-RhodoLED illuminator offers many advantages besides the claimed uniform light output (such as red light, more agile design, and the shorter incubation period of the corresponding photosensitizer, Ameluz). Thus the argument continues, it was error for Dr. Stec not to apportion his damages computation between the patented and unpatented features. *See Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014). Further, Biofrontera faults Dr. Stec for not taking into account BD-RhodoLED's more attractive pricing model and the availability of noninfringing alternatives (such as non-PTD

treatments and non-FDA-approved light sources) in defining the market for his lost profits analysis. Biofrontera also contests Dr. Stec's lost-profits analysis regarding the non-patent claims, arguing that there is no support for the premise that DUSA would have made all of Biofrontera's profits in the absence of the alleged tortious conduct. Finally, Biofrontera challenges Dr. Stec's methodology for quantifying the amount of lost profits because he did not include the profit loss for DUSA's BLU-U lamps, while he included sales of Ameluz in instances where there was no corresponding BF-RhodoLED sale.

The court agrees with DUSA that no apportionment of the lost profits between patented and unpatented components is required. This is not a case of a product "made of many different components, one or more of which components may be covered by an asserted patent, while other components are not." *LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 66 (Fed. Cir. 2012). Here, the accused product is an illuminator for PDT, and the claims are directed to the illuminator as a whole, or a method for using such an illuminator to perform PDT. See '991 patent, claim 1 ("An illuminator for diagnosing or treating a patient, comprising . . . ."; '289 patent, claim 1 ("A method for photodynamically diagnosing or treating a patient, comprising . . . .").

That the accused device possesses characteristics not recited in a limitation does not impair the scope of claims. On this point, *Mars, Inc. v. TruRx LLC*, 2016 WL 4034790 (E.D. Tex. Apr. 18, 2016), is instructive. In *Mars*, the court struck an expert report apportioning damages where the asserted claims were directed to a pet food formulation as a whole, even though the accused product also contained many unclaimed ingredients. *Id.*, at \*2.

In situations such as this – where the asserted patents cover the allegedly infringing products as a whole – the first Panduit<sup>1</sup> factor “does not require any allocation of consumer demand among the various limitations recited in a patent claim.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009). Instead, the patentee must show only that “demand existed for the ‘patented product,’ i.e., a product that is ‘covered by the patent in suit’ or that ‘directly competes with the

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<sup>1</sup> The *Panduit* factors, so named for *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978), is “[o]ne ‘useful, but non-exclusive’ method to establish the patentee’s entitlement to lost profits.” *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1284 (Fed. Cir. 2017). Under the *Panduit* test, a patentee is entitled to lost profits if it demonstrates:

- (1) demand for the patented product;
- (2) absence of acceptable non-infringing alternatives;
- (3) manufacturing and marketing capability to exploit the demand; and
- (4) the amount of profit it would have made.

*Id.* at 1285, citing *Panduit*, 575 F.2d at 1156.

infringing device.” *Id.* (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548-49 (Fed. Cir. 1995) (en banc)).

*Mars*, 2016 WL 4034790 at \*2 (footnote added). Similarly here, where the asserted claims cover the alleged illuminator as a whole, there is no need to apportion demand among features of the illuminator.<sup>2</sup>

The court also agrees with DUSA that Biofrontera’s objections to Dr. Stec’s but-for market analysis boil down to disputes of fact rather than questions of the reliability of his methodology. The premise of Dr. Stec’s but-for analysis – that the PTD market is a two-player market consisting of DUSA and Biofrontera (a view endorsed by Biofrontera’s own witnesses and counsel) – finds more than sufficient support in the record. In this circumscribed model, it is not unreasonable to assume that a doctor performing PTD would be limited to DUSA’s products in the hypothetical market absence of Biofrontera. Similarly, there is also sufficient support in Dr. Stec’s and Dr. Zamenhof’s reports for a jury to conclude that non-PDT treatments and non-FDA-approved lamps do not constitute acceptable non-infringing alternatives for *Panduit* purposes.

With respect to Dr. Stec’s computation of lost profits, the inclusion of sales of Ameluz in a convoyed sale scenario finds support in the record.

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<sup>2</sup> The BF-RhodoLED’s trumpeted red light, in any case, is found in dependent claims of the asserted patents.

A “convoyed sale” refers to the relationship between the sale of a patented product and a functionally associated non-patented product. A patentee may recover lost profits on unpatented components sold with a patented item, a convoyed sale, if both the patented and unpatented products “together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit.” *Rite-Hite Corp. v. Kelley Co. Inc.*, 56 F.3d 1538, 1550 (Fed. Cir. 1998).

*Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008).

Dr. Stec’s report notes that Ameluz and BF-RhodoLED are approved by the FDA as a combination therapy, and that several Biofrontera employees have testified that Ameluz and BF-RhodoLED are only offered for sale as companion products. In DUSA’s view, Biofrontera made sales of Ameluz only because it concurrently sold or offered to sell the infringing BF-RhodoLED. Biofrontera’s competing evidence – that certain Ameluz sales are not connected to a sale of BF-RhodoLED – goes to the issue of liability and not the relevance of the damages analysis. In the same vein, whether DUSA can prove entitlement to lost profits for Biofrontera’s sales as a result of the alleged trade secret misappropriation and other alleged tortious conduct is a question of causation for the factfinder.<sup>3</sup> *See Oahn Nguyen*

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<sup>3</sup> As the court noted in its order on Biofrontera’s summary judgment motion as to DUSA’s non-patent claims, Dr. Stec’s analysis explains that through the use of DUSA’s confidential information, particularly its customer lists, Biofrontera bypassed the high barriers of entry into the two-player market, and was thus able to sell Ameluz to customers that have never had to invest in its BF-RhodoLED lamp, and to focus on the key accounts to

*Chung v. StudentCity.com, Inc.*, 854 F.3d 97, 102 (1st Cir. 2017) (“Causation . . . generally presents a question of fact within ‘the special province of the jury.’”).

Finally, the court agrees with Biofrontera that a computation of DUSA’s lost profits must account for the costs DUSA would have incurred in making the hypothetical lost sales. *See Beckson Marine, Inc. v. NFM, Inc.*, 2007 WL 951706, at \*2 (W.D. Wash. Mar. 27, 2007) (“The measure of lost profits is the difference between the patent owner’s cost of production and the price at which the patent owner would have sold the product.”); *see also Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1266-1267 (Fed. Cir. 2013) (approving of lost profits calculations that “account[ed] for the costs associated with making those sales”). Here, where DUSA has asserted that the PTD illuminator and photosensitizer comprise a functional unit such that it may recoup the sales of the unpatented photosensitizer as a convoy sale, it must also account for the profit loss in the sales of the illuminator. The BLU-U profit loss being a known quantity, *see* DUSA’s Opp’n (dkt # 294) at 18, citing Stamm Report, Dr. Stec’s lost profits analysis must reflect DUSA’s hypothetical costs of production and sale.

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generate the highest return on investment. Under DUSA’s theory, absent this unfair business acceleration, DUSA would have captured the PDT sales made by Biofrontera as the only other player in the market.

**ORDER**

For the foregoing reasons, subject to the BLU-U profit loss limitation noted, Biofrontera's motion to exclude the opinion of Dr. Jeffrey Stec is DENIED.

**SO ORDERED.**

/s/ Richard G. Stearns  
**UNITED STATES DISTRICT JUDGE**